K090610
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MAR 1 3 2009

5 510(k) SUMMARY

1. **Submitted by:**

Hospira, Inc.
D-389 Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045
Contact: Yuliya Matlin MS, MBA
Phone :(224)212-4857
Fax: (224) 212-5401

2. **Date Prepared:** December 22, 2008

3. **Name/Classification of Device:** Transmitters and Receivers, Physiological Signal, Radiofrequency, Class II
DRG-21 CFR Parts 870.2910

4. **Trade Name of Proposed Device:** Hospira Vital Signs Wireless Monitoring System

5. **Predicate Devices:** Edwards LifeSciences Wireless Physiologic Monitoring System (K053016)
GMP/ Wireless Medicine LifeSync™ System (K030795)

6. **Proposed Device Description:**

The Hospira Vital Signs Wireless Monitoring System utilizes the Bluetooth® communications protocol. It will eliminate the multi-conductor, fixed length, shielded, reusable cable that typically acts as the interface between the patient's bedside monitor and the disposable transducer. The disposable transducer will simply plug into the system's remote transmitter unit, which will send its output signal to the system's receiver unit that is affixed to the bedside monitor. The wireless system is intended to operate at varying distances to accommodate typical layouts that exist within hospital operating rooms, critical care units, emergency rooms and catheterization lab suites.

7. **Statement of Intended Use:**

Hospira Vital Signs Wireless Monitoring System is indicated for use on patients requiring pressure monitoring. Hospira Vital Signs Wireless Monitoring System is intended to perform wireless transmission of blood pressure information to remote patient monitors from disposable pressure transducers.

8. Summary of Technological Characteristics of New Device Compared to Predicate Device

The subject and predicate devices are similar in design, materials of construction, components, intended use and labeling.

9. Statement of Substantial Equivalence

The Hospira Vital Signs Wireless System is substantially equivalent to the predicates with respect to the following characteristics:

Similarities:

1) Wireless transmission of physiological characteristics from the patient to the receiver monitor units.

2) Replaces the existing cabling between disposable physiological transducers and bedside monitors in hospital settings.

3) Utilization of the Bluetooth® Technology for wireless transmission of physiological signals.

The proposed modifications do not raise new issues of safety and/or effectiveness. Hospira Vital Signs Wireless Monitoring System meets the functional claims and intended use as described in product labeling and is as safe and effective in terms of substantial equivalence as the predicate devices described in the submission.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2009

Hospira, Inc.
c/o Ms. Yuliya Matlin, MS, MBA
Senior Associate, Regulatory Affairs-Devices
D-389 Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045

Re: K090610
Hospira Vital Signs Wireless Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (Two)
Product Code: DRG
Dated: March 04, 2009
Received: March 06, 2009

Dear Ms. Matlin:

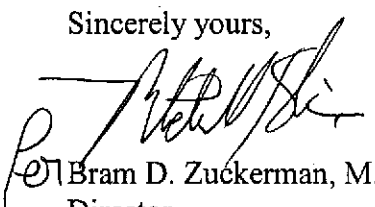
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090610

Indications for Use

510(k) Number (if known)

Device Name: **Hospira Vital Signs Wireless Monitoring System**

Indications for Use:

Hospira Vital Signs Wireless Monitoring System is indicated for use on patients requiring pressure monitoring. Hospira Vital Signs Wireless Monitoring System is intended to perform wireless transmission of pressure information to remote patient monitors from disposable pressure transducers.

Prescription Use X **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/13/09

(Division Sign-Off) For B Zuckerman
Division of Cardiovascular Devices
510(k) Number K090610